BRC Criteria Revised

Donna Shalala, secretary of the Department of Health and Human Services, has approved a revision of the criteria for listing a substance in the Biennial Report on Carcinogens (BRC) as "reasonably anticipated to be a human carcinogen." After formally approving the revised criteria, Secretary Shalala said, "The revisions will benefit public health—you and me—because [they] allow the use of information generated utilizing recent advances of biology at the level of the gene and living cell to aid in the hazard identification process."

The major change in the BRC is that the National Toxicology Program (NTP), headquartered at the NIEHS, will consider all relevant information—including mechanistic data—in determining whether to list a substance. These revisions also allow for removal of substances from the BRC when new information becomes available.

Relevant information includes, but is not limited to, dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive subpopulations, genetic effects, other data relating to mechanism of action, or factors that may be unique to a given substance. The last factor is especially important for the "reasonably anticipated to be a human carcinogen" category, where there may not be available evidence of carcinogenicity in humans or traditional laboratory studies using rats and mice, but where there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans. Conversely, there may be a substance for which there is evidence of carcinogenicity in laboratory rodents but compelling data indicating that the agent acts through mechanisms that do not operate in humans and that would therefore reasonably be anticipated not to cause cancer in humans.

Most substances listed in the BRC are contained in the "reasonably anticipated to be a human carcinogen" category based on studies performed on laboratory animals and linked to an increased incidence of malignant tumors. The categorization may also be based on a combination of malignant and benign tumors in two or more animal species, or in two or more studies, or the occurence of cancers of particularly unusual types or at sites that do not normally occur in the animals studied.

The revised criteria for listing a substance as "known to be a human carcinogen" are substantively unchanged from the former criteria, although the wording was slightly altered. To be listed as a known human carcinogen there must be "sufficient evidence of carcinogenicity from studies in humans that indicates a causal relationship between exposure to the agent, substance, or mixture and human cancer."

The public process for the review of listing criteria included participation or input from a broad base of interested parties from academia, industry, labor, federal, state, and local health agencies, and private organizations. The review included two public meetings by the NTP Board of Scientific Counselors, several reviews by the NTP Executive Committee, and a review by the Public Health Service's Environmental Health Policy Committee.

An expanded, formal review procedure for the inclusion or removal of substances in the BRC has also been established. This expanded procedure adds another comprehensive peer review step to this process with the establishment of a new standing subcommittee of the NTP Board of Scientific Counselors to provide outside peer review. Anyone may nominate a substance to be considered for listing or delisting in the BRC. All petitions received will undergo the expanded review process including reviews by NTP staff and NTP Executive Committee scientists as well as a review by the NTP Board of Scientific Counselors Subcommittee for the BRC, which will be held in public meetings.

Kenneth Olden, director of both the NTP and the NIEHS, said, "It makes good sense to fine-tune the process so that newly relevant scientific data is considered."

Biennial Report On Carcinogens Listing/Delisting Procedure

Petitions for listing or delisting an agent, substance, or mixture in the BRC may be submitted by any interested party and should be sent to the National Toxicology Program, Biennial Report on Carcinogens, MD WC-05, P.O. Box 12233, Research Triangle Park, NC 27709. Petitions must contain an explanation for listing or delisting the agent, substance, or mixture in the BRC as either a known human carcinogen or a reasonably anticipated human carcinogen. To the extent feasible, all appropriate background information and relevant data (e.g., scientific journal publications, NTP reports, IARC listings, exposure surveys, release inventories, etc.) that support the petition should be provided or fully referenced to permit retrieval. Petitions will be reviewed as expeditiously as possible. A list of new petitions for listing or delisting, which solicits public comment and input on the petitions, will be routinely published in appropriate publications, including the *Federal Register*, trade journals, and NTP Liaison office mail-outs.

Each petition received will be evaluated by a formal procedure that includes initial review by an NIEHS/NTP Review Group made up of senior scientists of the NIEHS/NTP staff, followed by consideration by the NTP Executive Committee's Working Group for the Biennial Report on Carcinogens and also by a standing NTP Board of Scientific Counselors Subcommittee for the BRC in public session. A detailed procedures document outlining the steps of a petition review can be obtained by contacting the NTP Liaison Office, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709.

ERRATUM

In the article entitled *Science from the Sea* in the May 1996 issue of *EHP*, James L. Boyer, director of the Mount Desert Island Biological Laboratory's Center for Membrane Toxicity Studies, was mistakenly identified under a photograph of David Evans. *EHP* regrets the error. Dr. Boyer is pictured below.